

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION FOR UNITED STATES LETTERS PATENT

**METHOD AND SYSTEM OF SENSING AIRFLOW
AND DELIVERING THERAPEUTIC GAS TO A PATIENT**

By:

Alonzo C. Aylsworth
19359 Ossenfort Ct.
Wildwood, MO 63038
Citizenship: USA

Lawrence C. Spector
4304 Small Drive
Austin, TX 78731
Citizenship: USA

Gregory R. Miller
4125 Mealer Lane
Washington, MO 63090
Citizenship: USA

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CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] None.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] Not applicable.

BACKGROUND OF THE INVENTION

Field of the Invention

[0003] Embodiments of the invention are directed to preferentially delivering therapeutic gas to a patient. More particularly, the embodiments are directed to delivering therapeutic gas to one, a combination, or all of a patient's left naris, right naris and mouth selectively.

Background of the Invention

[0004] Patients with respiratory ailments may be required to breathe a therapeutic gas, such as oxygen. The therapeutic gas may be delivered to the patient from a therapeutic gas source by way of a nasal cannula.

[0005] Delivery of therapeutic gas to a patient may be continuous, or in a conserve mode. In continuous delivery, the therapeutic gas may be supplied at a constant flow throughout the patient's breathing cycle. A significant portion of the therapeutic gas provided in continuous delivery is wasted, *i.e.* the therapeutic gas delivered during exhalation of the patient is lost to atmosphere. In order to overcome the wastefulness of continuous delivery, related art devices may operate in conserve mode using a conserver system.

[0006] A conserver may be a device which senses a patient's inspiration, and delivers a bolus of therapeutic gas only during inspiration. By delivering therapeutic gas only during inspiration, the amount of therapeutic gas lost to atmosphere may be reduced. Conserver systems of the related art may sense a patient's inspiration at one naris and delivery the bolus of therapeutic gas to the other naris, such as through a bifurcated nasal cannula. Alternatively, conserver devices of the related art may sense a patient's inspiration at the nares generally, and delivery a bolus of therapeutic gas to the nares generally, such as through a non-bifurcated (single lumen) nasal cannula.

[0007] Sensing at one naris and delivering to a second naris may not work properly in all situations. If the patient has a blocked naris, *e.g.* because of congestion or some physical abnormality, either the sensing may not operate properly or the delivery of therapeutic gas may be to the blocked naris. Sensing and/or delivery may also fail to operate properly if the nasal cannula becomes dislodged, such as during sleep. Even if a nasal cannula stays properly on the patient and neither naris is blocked, delivering the patient's entire prescription of therapeutic gas through a single naris may cause nasal irritation.

[0008] When sensing inspiration by monitoring both nares simultaneously, congestion and/or abnormalities in the nares may cause the system to not sense properly. Moreover, when delivering therapeutic gas to the nares generally, such as through a single lumen cannula, congestion and/or physical abnormalities of the nares may affect the volume inhaled in each naris, wasting therapeutic gas in some cases and not providing sufficient therapeutic gas in other cases.

SUMMARY OF SOME OF THE PREFERRED EMBODIMENTS

[0009] The problems noted above may be solved in large part by a method and system of individually sensing airflow of the breathing orifices of a patient, and preferentially delivering therapeutic gas to those breathing orifices. One exemplary embodiment may be a method

comprising sensing airflow of a first and second breathing orifice of a patient, delivering therapeutic gas to the first breathing orifice in proportion to the airflow of the first breathing orifice, and delivering therapeutic gas to the second breathing orifice in proportion to the airflow of the second breathing orifice.

[0010] The disclosed devices and methods comprise a combination of features and advantages which enable it to overcome the deficiencies of the prior art devices. The various characteristics described above, as well as other features, will be readily apparent to those skilled in the art upon reading the following detailed description, and by referring to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS .

[0011] For a detailed description of the preferred embodiments of the invention, reference will now be made to the accompanying drawings in which:

[0012] Figure 1 illustrates a preferential delivery system in accordance with embodiments of the invention;

[0013] Figure 2A illustrates, in shorthand notation, the system of Figure 1;

[0014] Figure 2B illustrates an alternative embodiment of the system of Figure 1;

[0015] Figure 2C illustrates yet another alternative embodiment of the system of Figure 1;

[0016] Figure 3 illustrates a preferential delivery system in accordance with alternative embodiments of the invention;

[0017] Figure 4A illustrates, in shorthand notation, the system of Figure 3;

[0018] Figure 4B illustrates an alternative embodiment of the system of Figure 3;

[0019] Figure 4C illustrates yet another alternative embodiment of the system of Figure 3; and

[0020] Figure 5 illustrates an alternative embodiment of the system of Figure 3 using fewer three-port valves.

NOTATION AND NOMENCLATURE

[0021] Certain terms are used throughout the following description and claims to refer to particular system components. This document does not intend to distinguish between components that differ in name but not function.

[0022] In the following discussion and in the claims, the terms “including” and “comprising” are used in an open-ended fashion, and thus should be interpreted to mean “including, but not limited to...”. Also, the term “couple” or “couples” is intended to mean either an indirect or direct electrical or mechanical connection. Thus, if a first device couples to a second device, that connection may be through a direct connection, or through an indirect connection via other devices and connections.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0023] Figure 1 illustrates a preferential delivery system 100 in accordance with at least some embodiments of the invention. The preferential delivery system 100 may be coupled to a therapeutic gas source 10 by way of a gas port 11. The therapeutic gas source 10 may be any suitable source of therapeutic gas, such as a portable cylinder, an oxygen concentration system or a permanent supply system as in a hospital. The selective delivery system also couples to a patient (not shown) by any of a variety of devices and systems by way of a variety of ports, such as narial ports 23, 25 and an oral port 27. For example, the preferential delivery system 100 may couple to a patient's nares by way of a nasal cannula. In accordance with embodiments of the invention, the preferential delivery system 100 monitors patient breathing and selectively delivers therapeutic gas to a left naris (LN), right naris (RN) and/or to the mouth (M) of the patient.

[0024] In accordance with at least some embodiments, the preferential delivery system 100 comprises both electrical components and mechanical components. In order to differentiate

between electrical connections and mechanical connections, Figure 1 (and the remaining figures) illustrate electrical connections between components with dashed lines, and fluid connections, *e.g.* tubing connections between devices, with solid lines. The preferential delivery system 100 in accordance with at least some embodiments of the invention comprises a processor 12. The processor 12 may be a microcontroller, and therefore the microcontroller may be integral with read-only memory (ROM) 14, random access memory (RAM) 16, a digital-to-analog converter (D/A) 18, and an analog-to-digital converter (A/D) 20. The processor 12 may further comprise communication logic 17, which allows the system 100 to communicate with external devices, *e.g.*, to transfer stored data about a patient's breathing patterns. Although a microcontroller may be preferred because of the integrated components, in alternative embodiments the processor 12 may be implemented by a stand-alone central processing unit in combination with individual RAM, ROM, communication D/A and A/D devices.

[0025] The ROM 14 may store instructions executable by the processor 12. In particular, the ROM 14 may comprise a software program that implements the various embodiments of the invention discussed herein. The RAM 16 may be the working memory for the processor 12, where data may be temporarily stored and from which instructions may be executed. Processor 12 may couple to other devices within the preferential delivery system by way of A/D converter 20 and D/A converter 18.

[0026] Preferential delivery system 100 also comprises three-port valve 22, three-port valve 24, and three-port valve 26. In accordance with embodiments of the invention, each of these three-port valves may be a five-volt solenoid operated valve that selectively fluidly couples one of two ports to a common port (labeled as C in the drawings). Three-port valves 22, 24 and 26 may be Humphrey Mini-Mizers having part No. D3061, such as may be available from the John Henry

Foster Co., or equivalents. By selectively applying voltage on a digital output signal line coupled to the three-port valve 22, the processor 12 may be able to: couple gas from the gas source 10 to the common port and therefore to the exemplary left naris; and couple the pressure sensor 28 to the common port and therefore the exemplary left naris. Likewise, the three-port valve 24, under command of the processor 12, may: couple gas from the gas source 10 to the narial port 23 and therefore the exemplary right naris; and couple the pressure sensor 30 to the narial port 23 and therefore the exemplary right naris. Further still, three-port valve 26 under command of the processor 12, may: couple gas from the gas source 10 to the narial port 25 and therefore the patient's mouth; and couple the pressure sensor 32 to the narial port 25 and therefore the mouth. When the pressure sensors 28, 30 and 32 are coupled to the respective ports, the processor 12 may read (through corresponding A/D converter 20 input signal lines) pressures indicative of airflow by the patient through the respective breathing orifice. Thus, the processor 12 may be able to determine when the patient is inhaling, and how much of the air drawn by the patient flows through each of the monitored breathing orifices.

[0027] Consider a situation where the preferential delivery system 100 couples to the nares of the patient by way of a bifurcated nasal cannula. As the patient inhales, outlet ports in the nasal cannula proximate to the openings of each naris experience a drop in pressure. The drop in pressure may be sensed through the nasal cannula and associated hosing by each of the pressure sensors 28 and 30. Likewise, a sensing and delivery tube may be placed proximate to the patient's mouth, and thus pressure sensor 32 may detect an oral inspiration by the patient. In accordance with embodiments of the invention, the preferential delivery system 100 senses whether a patient has airflow through a monitored breathing orifice, and delivers therapeutic gas to the location or locations where the therapeutic gas may be inhaled by the patient.

[0028] Still considering the situation where the patient couples to the preferential delivery system 100 by way of a bifurcated nasal cannula and a separate sensing and delivery tube for the mouth, if there is no obstruction to inhalation in either of the nares or the mouth, therapeutic gas may be provided to any one or a combination of the nares and the mouth. Here, the preferential delivery system 100 may beneficially alternate the delivery site periodically so as to reduce discomfort associated with the therapeutic gas. Should the nasal cannula become partially dislodged, therapeutic gas may be provided only to the naris where the outlet port of the nasal cannula is still in operational relationship to the naris. Should the patient's nares become congested or blocked, therapeutic gas may be provided to the naris that is open.

[0029] The embodiments of the invention described above may work equally well in systems delivering a continuous flow of therapeutic gas, as well as systems operating in a conserve mode. In the continuous mode of operation, each of the three-port valves 22, 24 and 26 may couple therapeutic gas to their respective breathing orifice for extended periods of time, *e.g.* several respiratory cycles. Periodically, therapeutic gas delivery may cease and the preferential delivery system 100 may monitor the breathing pattern of the patient. That is, one or more of the three-port valves 22, 24 and 26 may change valve position, thus coupling pressure sensors to their respective breathing orifices and stopping therapeutic gas flow. If a monitored breath or breaths show that none of the possible breathing orifices are blocked, then the system 100 may simply switch back to the continuous mode of operation. If the preferential delivery system cannot detect an inhalation for any one of the breathing orifices, continuous flow mode may be resumed without providing therapeutic gas to the breathing orifice experiencing a problem.

[0030] In alternative embodiments, the preferential delivery system 100 may operate in a conserve mode, delivering a bolus of gas during each inhalation of the patient. Consider for

purposes of explanation the left naris illustrated in Figure 1, as well as its associated three-port valve 22 and pressure sensor 28. Prior to an inspiration, the three-port valve 22 may couple the pressure sensor to the common port of three-port valve 22 and therefore the left naris. As the patient starts an inhalation, as sensed by the pressure sensor 28 and read by processor 12, the three-port valve 22 changes valve position (as commanded by processors 12) and couples the therapeutic gas source 10 to the common port (and effectively blocking the pressure sensor from the common port). For a period of time, *e.g.* 100 milli-seconds, therapeutic gas may flow to the exemplary left naris. When the desired bolus volume has been delivered, possibly as a function of flow rate of the therapeutic gas and time, the processor 12 may command the three-port valve 22 to its original state, again fluidly coupling the pressure sensor 28 to the left naris. During exhalation, again sensed by pressure sensor 28, the three-port valve 22 remains in the valve position coupling the pressure sensor to the common port, and therefore no therapeutic gas is delivered. This exemplary process is equally applicable to three-port valve 24 and pressure sensor 30 in operational relationship to the right naris, as well as three-port valve 26 and pressure sensor 32 in operational relationship to the patient's mouth. Thus, in conserve mode, the preferential delivery system 100 may detect whether the nares and/or mouth are open to therapeutic gas flow with each inspiration. In the event an inspiration on any particular delivery path is not detected, indicating a blockage or other gas delivery problem (such as a dislodged cannula), the preferential delivery system 100 may refrain from providing therapeutic gas to that breathing orifice.

[0031] Figure 2A illustrates the preferential delivery system 100 of Figure 1 in a shorthand notation, showing only pressure sensors 28, 30 and 32 coupled to the respective breathing orifices. Figure 2B illustrates alternative embodiments of the invention monitoring and delivering therapeutic gas only to the nares of a patient. In the embodiments of Figure 2B, if both the left

nasal and right nasal are open to flow the preferential delivery system 100 may deliver therapeutic gas to either nasal, to both nares, or in an alternating fashion. In the event that either the left or right nasal become clogged or blocked, or if the sensing and delivery tubing (such as a nasal cannula) become dislodged, the preferential delivery system may provide therapeutic gas to the nasal where airflow is sensed. Figure 2C illustrates alternative embodiments of the invention where two pressure sensors are used, but in this case only one pressure sensor is associated with the nares, and the second pressure sensor is associated with the mouth. In the embodiments of Figure 2C, a patient may utilize a single lumen cannula and a second sensing and delivery tube associated with the mouth. The preferential delivery system 100 may thus selectively provide therapeutic gas to the nares and/or to the mouth. In the event that either of the nares as a group or the mouth become blocked or otherwise unavailable for inspiration, the preferential delivery system 100 preferably provides therapeutic gas to the breathing orifice through which inhalation takes place.

[0032] Figure 3 illustrates a preferential delivery system 102 constructed in accordance with alternative embodiments of the invention. Like the system of Figure 1, the preferential delivery system 102 comprises a processor 12, possibly in the form of a microcontroller, comprising ROM 14, RAM 16, a D/A converter 18 and an A/D converter 20. Rather than pressure sensors, the preferential delivery system 102 may use flow sensors 40, 42 and 44. Thus, the preferential delivery system 102 may sense a portion of the flow associated with each breathing orifice. Consider for purposes of explanation the flow sensor 40 and three-port valves 46, 48 coupled to the left nasal. Three-port valve 46, under command of the processor 12, may: couple the gas source 10 to the common port and therefore the exemplary left nasal; and couple the flow sensor 40 to the common port and therefore the exemplary left nasal. Thus, during a period of time when the

preferential delivery system 102 provides therapeutic gas to the left naris (whether continuous or in a bolus form), the three-port valve 46 provides the therapeutic gas to the left naris and blocks the flow sensor. In a second valve position, the three-port valve 46 fluidly couples the flow sensor to the common port and therefore the exemplary left naris. However, and in accordance with embodiments of the invention, the flow sensor 40 may not be operational until gas can flow through the sensor. Three-port valve 48, in a first valve position, couples the flow sensor 40 to an atmospheric vent (marked ATM in the drawing), thus allow gas to flow through the flow sensor for measurement purposes. The three-port valve 48, in a second valve position, couples to a blocked port 49. Consider for purposes of explanation a preferential delivery system 102 operating in a conserve mode, where a bolus of gas is provided to one or more breathing orifices during inspiration. After a bolus has been delivered, the three-port valve 46 (and possibly the three-port valves 50 and 54) may change valve positions, thus fluidly coupling the flow sensor 40 to the common port and the exemplary left naris. If the flow sensor 40 outlet is not blocked, a portion of the therapeutic gas may reverse flow through the flow sensor 40 and out the atmospheric vent. Three-port valve 48 (as well as corresponding three-port valves 52 and 56) may be used to temporarily block reverse flow and loss of therapeutic gas, *i.e.* the valves may remain in a position that blocks flow for about 300 milliseconds after therapeutic gas delivery has stopped by a change of valve position by upstream three-port valves 46, 50 and 54. After the expiration of the period of time of possible reverse flow has ended, one or more of the three-port valves 48, 52 and 56 may change valve positions, thus allowing the flow sensors to sense airflow. The description with respect to the three-port valves 46, 48 and flow sensor 40 for the left naris is equally applicable for the corresponding structures for the right naris and mouth.

[0033] Figure 4A illustrates the preferential delivery system 102 of Figure 3 in a shorthand notation, showing only flow sensors 40, 42 and 44 coupled to their respective breathing orifice. Figure 4B illustrates alternative embodiments of the invention where only a patient's nares are used for sensing and delivery. In the embodiments of Figure 4B, if both the left naris and the right naris are open to flow, the preferential delivery system 102 may deliver therapeutic gas to either naris, to both nares, or in an alternating fashion. In the event that either the left or right naris become clogged or blocked, or if the sensing and delivery tubing become dislodged, the preferential delivery system may provide therapeutic gas only to the unblocked naris. Figure 4C illustrates further alternative embodiments where two flow sensors are used, but in this case only one flow sensor is associated with the nares, and the second flow sensor associated with the mouth. In the embodiments of Figure 4C, a patient may utilize a single lumen cannula, and a second sensing and delivery tube associated with the mouth. The preferential delivery system 100 may thus selectively provide therapeutic gas to the nares and/or the mouth. In the event that either of the nares as a group or the mouth become blocked or otherwise unavailable for inspiration, the preferential delivery system 102 preferably provides therapeutic gas to the open breathing orifice.

[0034] Figure 5 illustrates alternative embodiments of the invention utilizing flow sensors, but reducing the number of three-port valves used. The electrical components have been omitted from Figure 5 for purposes of clarity. In particular, Figure 5 illustrates that the three three-port valves 48, 52 and 56 of Figure 3 may be replaced by a single three-port valve 58. Blocking reverse flow through the flow sensors in the embodiments of Figure 5 may be accomplished by single three-port valve 58. Relatedly, opening the second port of each of the flow sensors to the atmosphere vent so that flow may be detected may likewise be accomplished with a single three-port valve 58.

[0035] The embodiments discussed to this point control therapeutic gas flow in a boolean fashion. That is, therapeutic gas is either delivered to a breathing orifice, or the preferential delivery systems 100, 102 refrain from delivering therapeutic gas to a breathing orifice. However, alternative embodiments of the invention, which may be implemented using any of the exemplary embodiments described above, may control flow to each breathing orifice in proportion (either direct or inverse) to the amount of airflow drawn by that breathing orifice. Consider, for purposes of explanation, the pressure and flow sensor embodiments illustrated by Figures 2B and 4B. For a variety of reasons, such as congestion, physical abnormalities, periodic swelling of the nasal tissue, and the like, the amount of air flow drawn by a patient during inhalation through the nares may not be equal. By detecting a pressure and/or detecting a portion of the air flow through each naris, the preferential delivery systems 100, 102 may quantify the relationship between the air flow as between the nares. For example, the left naris of an exemplary patient may carry 20% of the airflow, and the right naris of a patient may carry the remaining 80% of the air flow. In the embodiments discussed above, therapeutic gas may only be delivered to the right naris, carrying the bulk of the airflow. In the alternative embodiments, the selective delivery systems 100, 102 may proportion delivery of therapeutic gas. In the example of an 20-80 split between the left naris and the right naris respectively, the preferential delivery system 100, 102 may correspondingly proportion therapeutic gas flow 20% to the left naris and 80% to the right naris, or vice-versa. As the patient's left naris becomes less congested (or the patient changes head position that affects air flow or swelling, the preferential delivery system may likewise change the proportion of therapeutic gas flow. Referring again to Figure 3, proportioning therapeutic gas flow may be accomplished by pulse width modulating each of the three-port valves 46, 50 and 54 by the processor 12. In an exemplary situation where a patient's left naris carries only 20% of the total

airflow and control is a direct proportion, the electrical signal from the processor 12 to the three-port valve 46 may be pulse width modulating at a duty cycle where only 20% of the therapeutic gas is delivered to the left naris. Although the discussion with respect to the alternative embodiments where therapeutic gas may be proportioned between breathing orifices focused only on proportioning the nares, the proportioning may likewise be done between the nares in general and the mouth, or all three breathing orifices.

[0036] In all of the embodiments, in the event an inhalation is not detected through any breathing orifice, an alarm may be sounded. Relatedly, if the preferential delivery systems sense an apnea event, an alarm may be sounded. Moreover, the patient's breathing patterns may be stored, such as in RAM 16, and communicated to external devices through communication port 17.

[0037] The above discussion is meant to be illustrative of the principles and various embodiments of the present invention. Numerous variations and modifications will become apparent to those skilled in the art once the above disclosure is fully appreciated. For example, while the use of a cannula, at least with respect to coupling the preferential delivery system to the nares, has been discussed, this is only exemplary and any system and method by which the therapeutic gas is fluidly coupled from the preferential delivery system to the breathing orifices of the patient may be equivalently used. A single lumen cannula may be operable in some situations with respect to the nares. Likewise, a bifurcated nasal cannula may be used with respect to the nares. Alternatively, a cannula may be used where the sensing lines couple to the flow sensors are separate and distinct from the lines in which therapeutic gas is delivered proximate to the breathing orifices. Further, while the various embodiments described use electrical components as the control system, other pneumatic/mechanical systems may be equivalently used. It is intended that the following claims be interpreted to embrace all such variations and modifications.